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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,190	12/09/2001	Richard A. Dixon	NBLE:026US	2623

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EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,190

Applicant(s)

DIXON ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 20-49 and 55-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15-19, 50-54 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 12 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-69 are pending. Claims 20-49 and 55-66 are withdrawn. Claims 1-19, 50-54 and 67-69 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicant needs to amend the first line of the specification to recite that this application is a 371 of PCT/US00/05915 filed 03/08/2000 which claims benefit of 60/123,267 filed 03/08/1999.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant

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application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

This application contains claims 20-49 and 55-66 drawn to an invention nonelected with traverse in Paper No. 7/14/2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: Figures 2, 3, 4 and 5 present sequences but the Brief description of the Figures does not identify those sequences by using a sequence identifier.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

Claim Rejections - 35 USC § 112

Claims 1-11, 13, 15-19, 50-54 and 67-69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/14/2004. Applicant's arguments filed 10/28/2004 have been considered but are not deemed persuasive.

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Applicant asserts that the current claims have been amended to specify that the enzyme catalyzes the aryl migration of a flavanone to form an isoflavanone intermediate or an isoflavone comprising at least about 97% amino acid identity to the polypeptide encoded by nucleotide 36 to 1598 of SEQ ID NO: 1 and/or nucleotide 92 to nucleotide 1657 of SEQ ID NO: 4, and that the claim therefore recites concrete structural features (response page 11 part B).

However, in view of the “and” at Claim 1, line 36, rejection is maintained. SEQ ID NO: 1 and SEQ ID NO: 4 have 63.6 % sequence identity to each other. Figure 5 shows an alignment of the amino acid sequence encoded by SEQ ID NO: 1 and 4. A count of the residues that vary shows that 103 of the 522 amino residues are not shared between the two peptides yielding an amino sequence identity of about 80%, and thus the two polypeptides are not close enough in sequence identity to each other to physically permit any one amino acid sequence to have 97% sequence identity to both. Applicant fails to describe a DNA segment that meets these impossible claim limitations.

Claims 1-11, 13, 15-19, 50-54 and 67-69 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transforming a plant species to express an enzyme that catalyzes the aryl migration of a flavanone to form an isoflavanone intermediate or an isoflavone comprising at least about 97% amino acid identity to the polypeptide encoded by nucleotide 36 to 1598 of SEQ ID NO: 1 or nucleotide 92 to nucleotide 1657 of SEQ ID NO: 4, does not reasonably provide enablement for a method of transforming a plant species to express an enzyme that catalyzes the aryl migration of a flavanone to form an isoflavanone intermediate or an isoflavone comprising at least about 97% amino acid identity to the polypeptide encoded by nucleotide 36 to 1598 of SEQ ID NO: 1 and

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nucleotide 92 to nucleotide 1657 of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/14/2004. Applicant's arguments filed 10/28/2004 and the Dixon Declaration filed 10/18/2004 have been considered but are not deemed persuasive.

Applicant asserts that the claims are now enabled in view of Applicant's amendments and the Declaration of Dr. Dixon (response pages 12-13 part C).

As discussed above, Applicant has not taught how to make a DNA segment encoding a polypeptide sequence that can have 97% sequence identity to two other polypeptide sequences that vary with each other by 80%. Therefore, the instantly claimed methods, plants and seeds are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13, 15-19, 50-54 and 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 50, 54 and 67-69 are drawn to an enzyme that has both 97% sequence identity to the polypeptide encoded by nucleotides 36 to 1598 of SEQ ID NO: 1 and nucleotides 92 to 1657 of SEQ ID NO: 4, however SEQ ID NO: 1 and SEQ ID NO: 4 have 63.6 % sequence identity to each other. Figure 5 shows an alignment of the amino acid sequences encoded by SEQ ID NO: 1 and 4. A count of the amino acid residues that vary shows that 103 of the 522

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amino residues are not shared between the two peptides yielding an amino sequence identity of about 80%, and thus the two polypeptides are not close enough in sequence identity to each other to physically permit any one amino acid sequence to have 97% sequence identity to both; hence it is unclear what is being claimed.

Claim Rejections - 35 USC § 101

Claims 67-69 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed plants and seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claims 67-69 are drawn to parts such as seeds and progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Applicant asserts that the amendments to Claims 67-69 have overcome the product of nature rejection (response page 13 part E).

The Examiner respectfully disagrees. The amendment to the claim does not overcome the product of nature rejection because it does not state that the seeds or progeny comprise the

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recombinant DNA as stated and in view of arguments previously presented (see supra). If the Claims were amended to recite "Transgenic" or "Transformed" before the first word of each of Claims 67-69 the rejection would be obviated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-11, 13, 15-19, 50-54 and 67-69 are not allowed.

Claim 12 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
January 5, 2004



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